

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of the Claims:

1 (currently amended). A method for producing a controlled release matrix, comprising co-extruding through an extruder a composition comprising a dry mixture of at least one pharmaceutically active agent and at least one starch, wherein the temperature at the orifice of the extruder during the extrusion process is below 100°C under normal pressure, and wherein the co-extruding is under sheer force, temperature and pressure conditions such that the starch in the extruded controlled release matrix is vitrified.

Claims 2 and 3 (canceled).

4 (currently amended). The method of claim 1 ~~claim 3~~, wherein up to 15% by weight water is added to the composition ~~dry mix~~ prior to co-extruding.

5 (previously presented). The method of claim 1, wherein the matrix is water-insoluble.

6 (previously presented). The method of claim 1, wherein the co-extruding is under shear force, temperature, and pressure conditions to achieve glass transition of the starch.

Claims 7-9 (canceled).

10 (currently amended). A controlled release matrix produced by the method of claim 1, 4, 5, 20, 21 or 22 ~~claim 1, 2, 3, 4, 5, 20, 21 or 22~~.

Claims 11-15 (canceled).

16 (previously presented). The matrix of claim 10, wherein the release of the pharmaceutically active agent from the matrix substantially follows the lapidus rule.

17 (previously presented). The matrix of claim 10, wherein the release of the pharmaceutically active agent from the matrix is over 24 hours or more.

18 (previously presented). The matrix of claim 10, wherein the pharmaceutically active agent is present in the matrix as a liquid.

Claim 19 (canceled).

20 (previously presented). The method of claim 1, further comprising processing the matrix into granulates or into a mono-block pharmaceutical dosage form.

21 (previously presented). The method of claim 1, wherein the temperature in the feed area of the extruder is about 65°C, the temperature in the screw area is about 80°C, and the temperature in the die is about 98°C.

22 (previously presented). The method of claim 1, wherein the starch is selected from the group consisting of tapioca starch, wheat starch, potato starch, corn starch, acetylic starch, partially pregelatinized starch, wax corn starch, amylo corn starch, and a mixture of any of the foregoing.

23 (previously presented). The matrix of claim 10, wherein the pharmaceutically active agent is present in the matrix as a solid.

24 (previously presented). The matrix of claim 10, wherein the pharmaceutically active agent is dissolved in the matrix.

25 (previously presented). A controlled release matrix, comprising at least one starch and at least one pharmaceutically active agent, wherein the starch in the matrix is vitrified, and wherein the starch and pharmaceutically active agent were co-extruded.

26 (previously presented). The matrix of claim 25, wherein the matrix is free of pores.

27 (previously presented). The matrix of claim 25, which is water-insoluble.

28 (previously presented). The matrix of claim 25, wherein the pharmaceutically active agent is present in the matrix as a liquid.

29 (previously presented). The matrix of claim 25, wherein the pharmaceutically active agent is present in the matrix as a solid.

30 (previously presented). The matrix of claim 25, wherein the pharmaceutically active agent is dissolved in the matrix.

31 (previously presented). The matrix of claim 25, wherein the release of the pharmaceutically active agent from the matrix substantially follows the lapidus rule.

32 (previously presented). The matrix of claim 25, wherein the release of the pharmaceutically active agent from the matrix is over 24 hours or more.